

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE  
ACTING AS THE DESIGNATED/ELECTED OFFICE

In re: Patent application of John D. LAMBRIS

U.S. Appl. No. 10/528,496

I.A. No. PCT/US03/29653

I.A. Filing Date: 22 September 2003 (22.09.2003)

Confirmation No.: 4405

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IMPROVED ACTIVITY

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**INFORMATION DISCLOSURE STATEMENT**

Pursuant to 37 C.F.R. §1.56 and in accordance with 37 C.F.R. §§1.97-1.98, the references listed below and on the accompanying substitute Form PTO-1449 are being identified in the above-captioned application. In accordance with the *Official Gazette* Notice of August 2003 regarding 37 C.F.R. § 1.98(a)(2)(i), copies of U. S. patent references are not enclosed.

The references identified as Cite Nos. 9, 10 and 11 were cited in the International Search Report in corresponding International Application No. PCT/US03/29653. A copy of the International Search Report is enclosed for the Examiner's information.

<p align="center"><b>CERTIFICATE OF MAILING UNDER 37 C.F.R. 1.10</b></p> <p><b>EXPRESS MAIL Mailing Label Number:</b></p> <p>Date of Deposit: <u>2/2/07</u></p> <p>I hereby certify that this correspondence, along with any paper referred to as being attached or enclosed, and/or fee, is being deposited with the United States Postal Service, "EXPRESS MAIL-POST OFFICE TO ADDRESSEE" service under 37 C.F.R. 1.10, on the date indicated above, and addressed to: Mail Stop PCT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450</p> <p>Signature of person mailing page: <u>Karen M. Spina</u></p> <p>KAREN M. SPINA</p> <p>Type or print name of person</p>
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The Examiner is respectfully requested to review the items listed on the substitute PTO Form 1449 and make them of record in the instant application as required by M.P.E.P. §609.

The Information Disclosure Statement transmitted herewith is being filed after three months of the filing date of this national application or the date of entry of the national stage as set forth in § 1.491 in an international application, but before the mailing date of the first Office Action on the merits. Accordingly, no certification, petition, or fee should be required. However, should a fee be due, please charge the fee to Deposit Account No. 50-0573.

This Information Disclosure Statement should not be construed as a representation that the cited references are material or prior art, or that more relevant references do not exist.

Respectfully submitted,

Date: 2/2/2007

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SUBSTITUTE FORM PTO-1449 U.S. DEPARTMENT OF COMMERCE U.S. PATENT AND TRADEMARK OFFICE  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>	ATTY. DOCKET NO. 46483-0001-00-US 229798	APPLICATION NUMBER 10/528,496 (I.A. PCT/US03/29653)
	FIRST NAMED INVENTOR John D. Lambris	
	FILING DATE To be assigned (I.A. 22 SEPT 2003)	ART UNIT To be assigned

## U.S. PATENT DOCUMENTS

EXAMINER INITIALS	Cite No.	DOCUMENT NUMBER	PUBLICATION DATE (MM/DD/YYYY)	NAME OF PATENTEE OR APPLICANT OF CITED DOCUMENT	PAGES, COLUMNS, LINES, WHERE RELEVANT PASSAGES OR RELEVANT FIGURES APPEAR
		Number-Kind Code (if known)			
/MA/	1	4,299,838	11/10/1981	Durlach	
↓	2	4,576,750	03/18/1986	Pitzenberger	
	3	4,807,097	09/26/1989	Makovec, et al.	
	4	5,167,960	12/01/1992	Ito, et al.	
	5	5,256,642	10/26/1993	Fearon, et al.	
	6	5,776,970	07/07/1998	Shechter, et al.	
	7	6,169,057	01/02/2001	Lovatt	
	8	6,214,790 B1	04/10/2001	Richelson, et al.	
↓	9	6,319,897 B1	11/20/2001	Lambris, et al.	
/MA/	10	US 2001/0023066 A1	09/20/2001	Kinders, et al.	

## FOREIGN PATENT DOCUMENTS

EXAMINER INITIALS	Cite No.	FOREIGN PATENT DOCUMENT	PUBLICATION DATE (MM/DD/YYYY)	NAME OF PATENTEE OR APPLICANT OF CITED DOCUMENT	PAGES, COLUMNS, LINES, WHERE RELEVANT PASSAGES OR RELEVANT FIGURES APPEAR	T
		Country Code-Number-Kind Code (if known)				
/MA/	11	WO 99/13899 A1	03/25/1999	TRUSTEES OF THE UNIVERSITY OF PENNSYLVANIA		
/MA/	12	WO 91/16345 A1	10/31/1991	RIJKSUNIVERSITEIT TE UTRECHT		
/MA/	13	WO 95/23512	08/09/1995	ALEXION PHARMACEUTICALS, INC.		
EXAMINER SIGNATURE		/Maury Audet/		DATE CONSIDERED	06/21/2010	

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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### NON PATENT LITERATURE DOCUMENTS

EXAMINER INITIALS	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), Publisher, city and/or country where published	T
/MA/	14	BOWIE et al., "Deciphering the Message in Protein Sequences: Tolerance to Amino Acid Substitutions", <i>Science</i> 247:1306-1310 (1990)	
	15	FIANE, et al., "Prolongation of Ex Vivo-Perfused Pig Xenograft Survival by the Complement Inhibitor Compstatin", <i>Transplantation Proceedings</i> 31:934-935 (1999)	
	16	FIANE, et al. "Compstatin, a peptide inhibitor of C3, prolongs survival of ex vivo perfused pig xenografts", <i>Xenotransplantation</i> 6: 52-65 (1999)	
	17	FIANE, et al., "Modulation of Fluid-Phase Complement Activation Inhibits Hyperacute Rejection in a Porcine-to-Human Xenograft Model", <i>Transplantation Proceedings</i> 32:899-900 (2000)	
	18	FURLONG, et al., "C3 activation is inhibited by analogs of compstatin but not by serine protease inhibitors or peptidyl $\alpha$ -ketoheterocycles", <i>Immunopharmacology</i> 48:199-212 (2000)	
	19	KALLI, et al., "Therapeutic uses of recombinant complement protein inhibitors", <i>Springer Seminars in Immunopathology</i> 15:417-431 (1994)	
	20	KLEPEIS, et al., "Predicting Peptide Structures Using NMR Data and Deterministic Global Optimization", <i>Journal of Computational Chemistry</i> 20 (13):1354-1370 (1999)	
	21	KLEPEIS, et al., Integrated Computational Experimental Approach for Lead Optimization and Design of Compstatin Variants with Improved Activity", <i>J. Am. Chem. Soc.</i> 125:8422-8423 (2003)	
	22	MALLIK, et al., "Conformational Interconversion in Compstatin Probed With Molecular Dynamics Simulations", <i>PROTEINS: Structure, Function, and Genetics</i> 52:130-141 (2003)	
	23	MORIKIS, et al., "Solution structure of Compstatin, a potent complement inhibitor", <i>Protein Science</i> 7:6190-627 (1998)	
	24	MORIKIS, et al., "Design, Structure, Function and Application of Compstatin", <i>Bioactive Peptides in Drug Discovery and Design: Medical Aspects</i> , J. Matsoukas and T. Mavromoustakos (Eds) IOS Press, pp. 235-246 (1999)	
	25	MORIKIS, et al., "The Structural Basis of Compstatin Activity Examined by Structure-Function-based Design of Peptide Analogs and NMR", <i>The Journal of Biological Chemistry</i> 277 (17):14942-14953 (2002)	
	26	MORIKIS, et al., "Structural aspects and design of low-molecular-mass complement inhibitors", <i>Biochemical Society Transactions</i> 30 (6):1026-1036 (2002)	
	27	NILSSON, et al., "Compstatin Inhibits Complement and Cellular Activation in Whole Blood in Two Models of Extracorporeal Circulation", <i>Blood</i> 92 (5):1661-1667 (1998)	
	28	NGO, et al., "Computational Complexity, Protein Structure Prediction, and the Levinthal Paradox", <i>The Protein Folding Problem and Tertiary Structure Prediction</i> , pp. 492-495 (1994)	
/MA/	29	SAHU, et al., "Inhibition of Human Complement by a C3-Binding Peptide Isolated from a Phage-Displayed Random Peptide Library", <i>Journal of Immunology</i> 157:884-891 (1996)	
EXAMINER SIGNATURE		/Maury Audet/	DATE CONSIDERED
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/MA/	30	SAHU, et al., "Binding Kinetics, Structure-Activity Relationship, and Biotransformation of the Complement Inhibitor Compstatin", <i>The Journal of Immunology</i> 165:2491-2499 (2000)	
↓	31	SAHU, et al., "Compstatin, a peptide inhibitor of complement, exhibits species-specific binding to complement component C3", <i>Molecular Immunology</i> 39:557-566 (2003)	
	32	SCHASTEEN, et al., "Synthetic Peptide Inhibitors Of Complement Serine Proteases -III. Significant Increase In Inhibitor Potency Provides Further Support For The Functional Equivalence Hypothesis", <i>Molecular Immunology</i> 28 (1/2):17-26 (1991)	
	33	SOULIKA, et al., "Inhibition of Heparin/Protamine Complex-Induced Complement Activation by Compstatin in Baboons", <i>Clinical Immunology</i> 96 (3):212-221 (2000)	
	34	SOULIKA, et al., "Studies of Structure-Activity Relations Of Complement Inhibitor Compstatin", <i>The Journal of Immunology</i> 170:1881-1890 (2003)	
	35	ZACHARIAS, et al., "Cation- $\pi$ interactions in ligand recognition and catalysis", <i>Trends in Pharmacological Sciences</i> 23 (6):281-287 (2002)	
↓	36	BABITZKE, et al., "Structural Features of L-Tryptophan Required for Activation of TRAP, the trp RNA-binding Attenuation Protein of <i>Bacillus subtilis</i> ", 270 (21):12452-12456 (1995)	
/MA/	37	BEENE, et al., "Cation- $\pi$ Interactions in Ligand Recognition by Serotonergic (5-HT <sub>3A</sub> ) and Nicotinic Acetylcholine Receptors: The Anomalous Binding Properties of Nicotine", <i>Biochemistry</i> 41:10262-10269 (2002)	
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